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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/620,651	07/16/2003	Jan Markussen	4341.224-US	1417

23650 7590 06/27/2006

NOVO NORDISK, INC.
PATENT DEPARTMENT
100 COLLEGE ROAD WEST
PRINCETON, NJ 08540

EXAMINER	
CHANDRA, GYAN	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 06/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/620,651	MARKUSSEN ET AL.	
	Examiner	Art Unit	
	Gyan Chandra	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-136* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-136* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *7/16/2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/16/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments, And/Or Claims

Claims 1-136 are pending and are under examination.

Specification

At page 1, line 9, the specification attempts to incorporate by reference the contents of Danish application 0276/95. The incorporation of essential material in the specification by reference to an unpublished U.S. application, foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference, if the material is relied upon to overcome any objection, rejection, or other requirement imposed by the Office. The amendment must be accompanied by a statement executed by the applicant, or a practitioner representing the applicant, stating that the material being inserted is the material previously incorporated by reference and that the amendment contains no new matter. 37 CFR 1.57(f).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir.

1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-136 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-95 of U.S. Patent No. 5,750,497. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter claimed in the instant application is a pharmaceutical composition comprising a sodium phosphate buffer for the treatment of diabetes comprising a therapeutically effective amount of various derivatives of insulin or hexameric insulin complex in which (i) many different residues could be modified and (ii) each derivative lipophilic substituent is bound to either the N-terminus amino acid of the B-chain or to the C-terminus amino acid, and a method of treating diabetes in a patient in need of such treatment comprising administering the said pharmaceutical composition, whereas claims 1-95 of the U.S. Patent No. 5,750,497 are drawn to insulin derivatives and a pharmaceutical composition. The instant invention does not require that the pharmaceutical composition comprising insulin derivatives have a preservative or a pH range of 6.5-8.5. Therefore, the scope of the instant invention is different than the U.S Patent No. 5,750,497.

Claims 1-136 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-115 of U.S. Patent No. 6,011,007. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter claimed in the instant application is a pharmaceutical composition comprising a sodium phosphate buffer for the treatment of diabetes comprising a therapeutically effective amount of various derivatives of insulin or hexameric insulin complex in which (i) many different residues could be modified and (ii) each derivative lipophilic substituent is bound to either the N-terminus amino acid of the B-chain or to the C-terminus amino acid, and a method of treating diabetes in a patient in need of such treatment comprising administering the said pharmaceutical composition, whereas claims 1-115 of the U.S. Patent No. 6,011,007 are drawn to insulin derivatives and a pharmaceutical composition. The instant invention does not require that the pharmaceutical composition comprising insulin derivatives any preservative or a pH range of 6.5-8.5. Therefore, the scope of the instant invention is different than the U.S Patent No. 6,011,007.

Claims 1-136 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-23 of U.S. Patent No. 6,251,856. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter claimed in the instant application is a pharmaceutical composition comprising a sodium phosphate buffer for the treatment of diabetes comprising a therapeutically effective amount of various derivatives of insulin

or hexameric insulin complex in which (i) many different residues could be modified and (ii) in which each derivative lipophilic substituent is bound to either the N-terminus amino acid of the B-chain or to the C-terminus amino acid, and a method of treating diabetes in a patient in need of such treatment comprising administering the said pharmaceutical composition, whereas claims 1-23 of the U.S. Patent No. 6,251,856 are drawn to insulin derivatives and a pharmaceutical composition. The instant invention does not require that the pharmaceutical composition comprising insulin derivatives any preservative or a pH range of 6.5-8.5. Therefore, the scope of the instant invention is different than the U.S Patent No. 6,251,856.

Claims 1-136 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-23 of U.S. Patent No. 6,620,780. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter claimed in the instant application is a pharmaceutical composition comprising a sodium phosphate buffer for the treatment of diabetes comprising a therapeutically effective amount of various derivatives of insulin or hexameric insulin complex in which (i) many different residues could be modified and (ii) in which each derivative lipophilic substituent is bound to either the N-terminus amino acid of the B-chain or to the C-terminus amino acid, and a method of treating diabetes in a patient in need of such treatment comprising administering the said pharmaceutical composition, whereas claims 1-23 of the U.S. Patent No. 6,620,780 are drawn to insulin derivatives, a pharmaceutical composition and a method of treating

diabetes in a patient in need there of. The instant invention does not require that the composition comprising insulin derivatives be in a mixture with an insulin analogue, which has a rapid onset of action. Therefore, the scope of the instant invention is different than the U.S Patent No. 6,620,780.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-136 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 12, 27, 47, 69, 95, and 117 recite " a derivative of a parent insulin having the following sequence". However, it is not clear if the derivative for the parent insulin have the sequence which is recited in the claims. The claims would be clear if they simply recited " an insulin derivative having the following sequence". The naturally occurring sequence of insulin is known in the art, including different species of insulin.

Claim 12 recites " a hexameric complex which contains a derivative of parent insulin", however, it is unclear that the composition which is claimed is a hexameric complex of insulin. From the review of the instant specification, it would appear that the different insulin molecules would form hexamers in the presence of zinc. However, it is not clear what a " hexameric complex which contains a derivative of parent insulin", would encompass. Is this a hexameric complex which contains 6 different components

which has the derivative inserted in it? Is this a hexameric complex where one member out of six is different which has a derivative inserted in it or other possible combinations? The metes and bounds of the claims cannot be determined, and therefore, the claims are indefinite.

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Hashimoto et al. (Pharm. Res. 6 : 171-176, 1989). Hashimoto et al teach that the addition of lipohilic groups to the amino acids B1 and B29 result in an extended effect and reduced immunogenicity (see page 175, right side column and abstract).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gyan Chandra whose telephone number is (571) 272-2922. The examiner can normally be reached on 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Gyan Chandra, Ph.D.
Art Unit 1646
12 June 2006
Fax: 571-273-2922

Eileen B. O'Hara

EILEEN B. O'HARA
PRIMARY EXAMINER